UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	8

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/225,904	Sidransky et al.
Examiner	**Group Art Unit**
Scott Houtteman	1656

X Responsive to communication(s) filed on *Jan 28, 2000*

X This action is **FINAL.**

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

X Claim(s) *1-11* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

Claim(s) _____ is/are allowed.

X Claim(s) *1-11* is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

X Information Disclosure Statement(s), PTO-1449, Paper No(s). Filed 1-5-99

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Applicant's response, filed 11/28/00, has been carefully considered with the following effect:

The objection and rejections of paragraphs 1A, 1B, Office action mailed 6/22/00, have been withdrawn in view of applicant's amendments.

The objections and rejections of paragraphs , Office action mailed 6/22/00, have been maintained.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Newly amended claims 1-11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 5 and 7-11 recite methods of treatment of a cell proliferative disorder "associated with expression" of either 5'ALT or p16 expression with a "reagent." The identity of the "reagent" and the steps of administration of the reagent are unclear.

The claims recite no specific disease. There are no specific structural characteristics for the reagent and no specific methods of administration. The claims do recite that the disorder is "associated" with the expression of a gene and that the treatment involves the administration of a reagent.

The claims go a far as describing the effects of the reagent as either inhibiting or stimulating gene expression, but these claims do not specify physical characteristics of the reagent, the mechanism by which the reagent acts, the degree of specificity in the reagents actions or any details on how the reagent is constructed or isolated.

Formally, the claims read on "poison" which would inhibit gene expression. However, it is clear that poison would have to general effects on the entire cell to be effective. What is not clear is the boundary between non effective reagents and effective reagents. Thus, lacking a specific characteristic of the reagent, and merely reciting effects, the skilled artisan is unclear on the scope of the limitation "reagent."

4. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not disclosed in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record.

5. Applicant argues that the skilled artisan would know how to identify a disorders by detecting correlations between gene expression or methylation patterns. This argument is not persuasive. The claims are NOT drawn merely to the identification of abnormal gene expression patterns in the cells of the claimed cell proliferative disorder. Rather, the claims are drawn to the much more difficult goal of "treatment" of these disorders.

Applicant argues that gene therapy is only one method within the scope of the claimed treatments. This argument is not persuasive. By pointing out that the claim scope is broader than gene therapy, this argument merely suggest that the claims need even greater enablement than a claim limited to gene therapy.

Applicant argues that the Stolberg article "provides several examples demonstrating the effectiveness of methods of gene therapy," for example in treating hemophilia and certain cancer patients.

This argument is not persuasive. Stolberg describes success only in cases in which the disease mechanism is well known. For example, in hemophilia, a specific gene product is missing, factor 8. The gene therapy is to provide this product. Another treatment described in Stolberg, the treatment for SCID, involves replaces the bone marrow cells from patients missing those cells which are the source of the patents immune system. In contrast, the claims of this case are drawn to "disorders" associated (in any possible way) with the expression of a gene.

The argument leaves out critical portions of Stolberg that teaches the difficult hurtles that need to be overcome to enable the successful examples in Stolberg. For example, Stolberg teaches "scientists have had trouble devising delivery vehicles, called vectors, that can direct genes into the proper cells and get them to function once they are there." The field of gene therapy has had some successes. However, these are all the results of specific treatments designed for specific diseases after determining the disease mechanism to be simply the absence of a gene products.

Is in not correct to argue that these hard-won successes mean that the field of gene therapy is transformed to one so predictable that generic guidelines, such as those of this specification, enable a reasonable number of "reagents" for "treatments" of vaguely defined "cell proliferative disorders." Accordingly, it would take undue experimentation to enable a reasonable number of treatments.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

7. Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Technology Center 1600 Fax numbers are (703) 305-3014 and 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Houtteman whose telephone number is (703) 308-3885. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday from 8:30 AM - 3:30 PM. The examiner can also be reached on alternate Wednesdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Scott Houtteman
March 12, 2001

SCOTT W. HOUTTEMAN
PRIMARY EXAMINER